Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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WASHINGTON, DC 20515–6143

April 27, 2000

The Honorable Jane Henney, M.D.
Commissioner for Food and Drugs
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, Maryland 20857

RE: Docket No. 00N-1200 and Docket No. 95N-0304

Dear Dr. Henney:

Pursuant to Rules X and XI of the Rules of the House of Representatives, the Committee on Government Reform has oversight of the Food and Drug Administration (FDA). As you know, the Committee has an ongoing investigation into the regulation of dietary supplements by Federal agencies including the FDA. It is important to assure that Americans have access to safe and health promoting dietary supplement products.

In writing the Dietary Supplement Health and Education Act (DSHEA), the Congress provided the FDA with the necessary authority to remove unsafe supplements from the market, a point that you have confirmed on several occasions in testimony before Congress. When FDA uses this authority, it is imperative that any actions be based on valid science.

On June 4, 1997, FDA proposed a regulation to limit the marketing of dietary supplements containing ephedrine alkaloids (ephedra products). This proposed rule arose from FDA concerns that ephedra products were causing adverse effects in consumers. A subsequent report that the General Accounting Office (GAO) published in July 1999, confirmed that, while there was some basis for concern, the portions of FDA's proposed rule that the GAO had audited did not have an adequate scientific basis.

Just as with all foods and dietary supplements, there is certainly a need to assure the safe use of products that contain ephedra. Many products that are consumed safely by millions of Americans, if not properly used, pose significant health risks. Expanded education on the importance of reading labels has saved many lives of those allergic to peanuts and other food substances which can create life-threatening reactions when consumed. Unfortunately, many

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consumers still do not read labels on dietary supplements and over-the-counter products and thus preventable adverse reactions occur. I was saddened to learn that many of the events reported showed evidence that consumers failed to follow clearly marked warnings and consumed products for which their preexisting health conditions were a contraindication.

Many responsible companies have worked with their trade associations and with medical and scientific experts to establish standards through trade guidance and by supporting state laws. In an effort to monitor the impact of these standards on product safety, several parties filed Freedom of Information Act (FOIA) requests beginning in 1997 to request any new adverse event reports concerning ephedra products that FDA received after the publication of the June 4, 1997 proposed rule. FDA has informed the parties requesting these records that the agency did not have sufficient resources to provide the records, and these records were not produced as required under the FOIA. This mismanagement of the FOIA process is completely unacceptable and must be rectified immediately. Please provide monthly updates to my staff on the status of FOIA requests and the resolution to the backlog of requests.

On April 3, 2000, FDA published a Federal Register Notice announcing the withdrawal of the portions of the 1997 proposed rule that the GAO audited. Other Notices published on the same day announced the availability of new adverse event reports for these products, solicited comments on this new information, announced a public forum to be held at a date to be specified in the future, and announced the availability of new guidance on the illegal marketing of street drug alternatives.

I commend you for withdrawing the portions of the 1997 proposed rule that were the subject of the GAO audit. However, it is clear that the process that FDA has proposed for public review of this new information will not permit the type of fully informed comments that the agency needs.

The FDA Notice stated that it has created a separate group of reports on ephedra products that were submitted to FDA from June 1, 1997, through March 31, 1999. The purpose of setting the March 31, 1999, cutoff date was to create "a closed set of data to analyze and prepare for public release." However, FDA failed to share this information with the public for an entire year. The agency also took ten months to fulfill a request I made in May 1999 for similar information. Between March 31, 1999, and March 31, 2000, FDA spent several months compiling the reports, and then spent several more obtaining reviews of these 140 AERs from within FDA and also from outside experts. FDA also obtained statements from outside experts reviewing the applicable published literature and the traditional uses of ephedra products, and assessing reporting rates for various types of products.

When FDA released the 140 AERs for public review on March 31, 2000, FDA had compiled several hundred pages of analysis and references, and had also collected information on another 130 adverse events that the agency has yet to analyze. All of this information, which FDA has described as approximately 10 linear feet of paper, was provided to the public for its review on March 31, 2000. FDA has also requested that the public provide the agency with "new usage

data, and new scientific information, including clinical trials" in order to assure that any future decisions with respect to ephedra products will be based on complete and adequate data. This new information is of critical importance to any review of ephedra products, but is not included in FDA's current record.

The public is being asked to undertake a review of approximately three times as much information as FDA reviewed in one year and to compile new information as well in just 45 days. I understand that the task of obtaining all of the information FDA has placed in this docket will take up to three weeks (half of the current comment period).

Given the sized of the task, and the importance to have adequate review, the 45 day comment period is considerably inadequate. I am requesting that this period be extended through December 31, 2000. The time that FDA has provided for public review is plainly not sufficient to achieve the task that FDA has stated as its goal – a thorough public review and discussion of the safety of ephedra products. I agree with the agency that this is a desirable and attainable goal. However, more time for public review is essential to this goal.

As FDA already recognizes, in order to have an informative public forum, FDA should allow at least one month after the close of the public comment period for public review of the comments before holding the public forum.

Finally, if FDA believes that current standards for these products are not sufficient to protect the public health and that new or additional standards are necessary, we encourage FDA to discuss its concerns with interested parties before FDA publishes any new proposal for ephedra products. Developing standards by consensus will help to assure that future issues of product safety are resolved in an expeditious manner.

The process that FDA has established for the ongoing review of ephedra products will not result in a fair and thorough review of the science. If necessary, in order to assure the scientific integrity of FDA's process, we will request that the GAO conduct an additional review of the scientific basis for any future FDA proposals for these products.

Please provide a response to the request for an extension by May 4, 2000. If you have any questions, please contact Ms. S. Elizabeth Clay at 202-225-5074.

Sincerely,

Dan Burton
Chairman